EXHIBIT 12

Hiatal dimensions were generally higher in Green III, especially on pelvic floor muscle contraction (PFMC, Table 1).

Table 1: Ultrasound findings in patients with Green type II and III cystoceles. Figures signify means and standard deviations.

Measure	Green type II (n=62)	Green type III (n=41)	P value
Hiatal area (rest)	17.71±4.28	20.24±5.42	0.014
Hiatal area (Valsalva)	30.69±7.73	33.73±8.93	0.079
Hiatal area (PFMC)	14.26±3.32	17.15±5.21	0.004
Levator avulsion defect	36%	66%	0.002
Abnormal slices on TUI	3.5±5.7	7.6±6.8	0.003

Conclusions:
This study sheds light on the possible mechanisms underlying the pathogenesis of cystocoele. It has been claimed that cystourethrocele is more often related to paravaginal defects (3). Our study shows contrary evidence in that a cystocele with an intact RVA is more likely to be associated with avulsion defects of the levator ani, the possible surrogate mechanism for a paravaginal defect, rather than a cystourethrocele. Thus, it seems that a Green 3 cystooele is the one that is more likely to be caused by birth related trauma.

References:
1. Am J Obstet Gynecol 1975;122:368 400.
2. Ultrasound Obstet Gynecol 2007;29:329 334
3. Obstet Gynecol 1981;57:357 62

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TRIAL OF A TISSUE FUSION TECHNOLOGY VERSUS TRADITIONAL LIGATION TECHNIQUES IN VAGINAL HYSTERECTOMY IN PATIENTS WITH UTERINE PROLAPSE

R. BRUNO, A. B. DICK, M. BIRDSALL, N. R. PETERSEN, R. MCLELLAN;
Lahey Clinic Fndn., Inc., Burlington, MA.

Consent obtained from patients: Yes
Level of support: Investigator initiated, partial funding
Work supported by industry: Yes

Objective:
An update of findings of a prospective randomized IRB approved study comparing a tissue fusion technology (Ligasure Impact using the Force Triad Energy Platform) versus traditional clamp and suture in vaginal hysterectomy in patients with uterine prolapse.

Background:
To date, 91 of the eventual 140 randomized patients between the ages of 42 and 85 have been treated in an university affiliated, tertiary care teaching hospital. 46 in the tissue fusion technology arm and 45 in the traditional clamp and suture arm.

Methods:
The first procedure time was defined from vaginal incision to removal of the uterus with satisfactory hemostasis. The second procedure time was the removal of the ovaries. Blood loss was estimated by the anesthesia service. Patients were evaluated postoperatively with a 0 to 10 visual analog pain score at 24, 48, and 72 hours.

Results:
The use of the tissue sealing device resulted in shorter surgery times for removal of the uterus. The mean time savings was 13.25 minutes (43% difference, P<0.001), 17.39 minutes in the tissue fusion arm versus 30.64 minutes in the clamp and suture arm. The removal of the ovaries also took less time with the tissure fusion technology. On average the tissue fusion technology required 10.50 minutes versus 22.50 minutes in the traditional group. A time savings of 12 minutes (53% difference, P<0.001). Blood loss was less in the tissue fusion technology arm 39.7 ml versus 95.0 ml in the clamp and suture arm (61% difference, P<0.001). There were statistically significant lower visual analog pain scores postoperatively in the tissue fusion arm versus the clamp and suture arm at 24 hours (2.70 vs 4.47, P<0.001), 48 hours (2.24 vs 3.72, P<0.001),and 72 hours (1.58 vs 3.36, P<0.001). Updated results will be presented at the time of the presentation.

Conclusions:
Results to date indicate that the tissue fusion technology is a viable alternative to traditional clamp and suture in vaginal hysterectomy in patients with uterine prolapse. The use of tissue fusion technology results in statistically significant lower operative times, blood loss, and postoperative pain scores.

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ULTRASOUND EVALUATION OF POLYPROPYLENE MESH CONTRACTION AT LONG TERM AFTER VAGINAL SURGERY FOR CYSTOCELE REPAIR

V. LETOUZEY[1], X. DEFFIEUX [2], J. LEVAILLANT [2], E. FAIVRE [3], R. DE TAYRAC [1], H. FERNANDEZ [2];
[1]CHU Caremeau, Nimes, France, [2]CHU Antoine Beclere, Clamart, France, [3]CHU Clamart, Clamart, France.

Consent obtained from patients: Yes
Level of support: Not applicable
Work supported by industry: No

Objectives:
To evaluate polypropylene mesh contraction after vaginal surgery for cystocele repair and to correlate mesh contraction with recurrence.

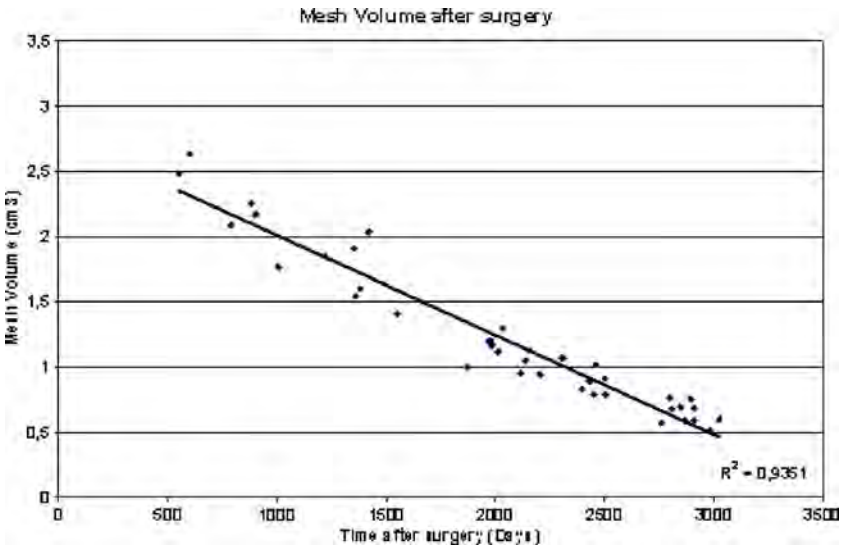
Background:
It has been shown that the use of mesh decrease the recurrence rate of cystocele in vaginal surgery[1]. Mesh contraction up to 50% has been already shown[2]. However, no study has been done to correlate mesh contraction and clinical outcome at long term.

Methods:
This is a retrospective study concerning 40 patients treated between 1999 and 2006. Cystocele repair was performed using the placement of polypropylene mesh (Gynemesh®, 6x12 cm) under the bladder in a tension free procedure. All patients had clinical exam and translabial 3D ultrasonography examination in 2008 which has focused on mesh size and location. Cystocele recurrence was defined by Ba point (POP Q, ICS) superior at 1 (stage 2 or 3). Volume and area datasets were analyzed to define the percentage of mesh contraction.

Results:
Mean age was 64 years (+/ 11). Mean time between ultrasound evaluation and surgery was 6 years (+/ 20 months). 3D Ultrasound reconstruction has been showed a mean contraction of 30%, 65%, 85%, at a mean follow up of 3 years (n 12), 6 years (n 16), 8 years (n 12) respectively. Furthermore, we observed a linear evolution of the contraction rate between 18 months and 9 years after the mesh implantation. There was no significant correlation between mesh position (bladder neck, pubis and mesh surface under the bladder) and clinical outcomes (as cystocele recurrence, prolapse symptoms or voiding dysfunction) ($p>.1$). We noted a significant correlation between vaginal thickness and vaginal mesh extrusion ($p<.05$).

Conclusions:
We observed an important mesh contraction at more than 5 years follow up with no significant correlation with cystocele recur rence. Ultrasound evaluation should be recommended for mesh contraction follow up and to compare polypropylene meshes.

References:
1. Nguyen JN, Burchette RJ. Outcome after anterior vaginal prolapse repair : A randomized controlled trial. Obstet Gynecol. 2008 Apr; 111 (4):891 898.
2. Tunn R, Picot A, Marschke J, Gauruder Burmester A. Sonomorphological evaluation of polypropylene mesh implants after vaginal mesh repair in women with cystocele or rectocele. Ultrasound Obstet Gynecol. 2007 Apr;29(4):449 52.



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PROSPECTIVE STUDY OF THE PERIGEE™ SYSTEM FOR TREATMENT OF CYSTOCELES OUR 5 YEAR EXPERIENCE.

A. RANE[1], K. KANNAN [1], A. CORSTIAANS [2];
[1]James Cook Univ., Townsville, Queensland, Australia, [2]THE TOWNSVILLE Hosp., Townsville, Queensland, Australia.

Consent obtained from patients: Yes
Level of support: Not applicable
Work supported by industry: No

Objectives:
The Perigee™ Transobturator Cystocele repair system (AMS) was designed and first used on the 10th of March 2004 in Townsville, Australia. This prospective study evaluates our 5 year experience with the PerigeeTM system assessing the efficacy and safety of this device for the management of anterior vaginal prolapse.

Materials:
Patients who underwent surgery with the Perigee™ system between March 2004 and June 2008 were followed up for cure rate, recurrence and complications

Methods:
The study involved answering a detailed questionnaire and POP Q assessments pre and post operatively at 6 weeks, 3 months, 6 months, 12 months and subsequently biannually.

Results:
A total of 350 patients underwent surgery with the Perigee™ system between March 2004 and June 2008. The duration of follow up varies from 6 months to 4 years. All patients had stage 3 and above cystoceles and 39 patients (11%) had a concomitant level 1 defect. There were no immediate life threatening complications associated with the procedure. Fourteen patients (4%) complained of a lump sensation post operatively but had a prolapse less than stage 2 while 6 (1.71%) patients had prolapse of grade 2 or more. Of the 14 patients, one patient required vaginal hysterectomy and McCaul's culdeplasty for grade 3 uterocervical prolapse. The other 13 patients were managed conservatively. Of the 6 patients with recurrence of > stage 2, two patients have had repeat surgery so far. The mesh erosion rate was 11.1% (39 pts) in this study. Thirty four patients required mesh excision and trimming under general anaesthesia while five patients were managed with outpatient trimming and vaginal oestrogen therapy. Of the 34 patients, 1 patient had an infected mesh that required